## WHAT IS CLAIMED IS:

1. Form B montelukast sodium characterized as having an x-ray powder diffraction pattern peak position substantially as shown:

| 2θ   | d spacing (A) | Intensity |
|------|---------------|-----------|
| 5.4  | 16.4          | S         |
| 5.7  | 15.6          | vs        |
| 9.5  | 9.3           | m         |
| 10.4 | 8.5           | m         |
| 17.1 | 5.2           | s         |
| 18.7 | 4.73          | s         |

2. A pharmaceutical composition comprising a therapeutically effective amount of montelukast sodium Form B of Claim 1 and a pharmaceutically acceptable carrier.

s

4.11

21.6

10

5

- 3. A method for the treatement of asthma or allergic rhinitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.
- 4. A method for the treatment of respiratory symptoms associated with viral bronchiolitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.
- 5. A method for the treatment of chronic urticaria which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

6. A method for the treatment of conjunctivitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

7. A method for the treatment of sinusitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

10

8. Montelukast sodium:acetonitrile monosolvate.

9. Montelukast sodium:acetonitrile monosolvate characterized by having <sup>13</sup>C solid-state CPMAS NMR chemical shifts in ppm at 72 (sharp triplet), 74 (sharp triplet), 179 (sharp doublet), and 182 (sharp doublet).

15 10. Montelukast sodium:acetonitrile monosolvate of Claim 8 further characterized by having X-ray powder diffraction peaks substantially as shown:

| 2θ   | d spacing (Å) | Intensity |
|------|---------------|-----------|
| 4.30 | 20.5          | vs        |
| 5.9  | 14.9          | S         |
| 6.2  | 14.3          | S         |
| 6.8  | 13.0          | w         |
| 7.3  | 12.0          | w         |
| 10.5 | 8.4           | m         |
| 11.0 | 8.0           | w         |
| 12.7 | 7.0           | m         |
| 16.2 | 5.5           | S         |
| 18.1 | 4.90          | w         |
| 18.7 | 4.74          | w         |
| 21.6 | 4.12          | w         |
| 23.4 | 3.80          | w         |

| 2 |
|---|
| 7 |

- 11. Monteclukast sodium:acetonitrile hemisolvate.
- 12. Montelukast sodium:acetonitrile hemisolvate of Claim 10 characterized by having <sup>13</sup>C solid-state CPMAS NMR chemical shifts in ppm at 27 (well resolved) and 55 (well resolved), referenced by setting the carbonyl resonance of glycine to 176.08.
- 13. Montelukast sodium:acetonitrile hemisolvate of Claim 10 characterized by having X-ray powder diffraction peaks substantially as shown:

| 2θ   | d spacing (Å) | Intensity |
|------|---------------|-----------|
| 4.57 | 19.3          | S         |
| 5.3  | 16.7          | S         |
| 5.6  | 15.7          | vs        |
| 6.5  | 13.6          | m         |
| 9.4  | 9.4           | m         |
| 10.3 | 8.6           | w         |
| 11.6 | 7.6           | m         |
| 14.1 | 6.3           | w         |
| 14.5 | 6.1           | m         |
| 15.1 | 5.8           | w         |
| 16.2 | 5.5           | m         |
| 17.0 | 5.2           | m         |
| 18.5 | 4.79          | s         |
| 20.8 | 4.26          | m         |
| 21.3 | 4.17          | S         |

14. A method for the preparation of montelukast sodium Form A substantially free of amorphous montelukast sodium comprising: 1) collecting

montelukast sodium:acetonitrile monosolvate; and 2) removing acetonitrile from the collected monosolvate.

15. A method for the preparation of montelukast sodium Form A substantially free of amorphous montelukast sodium comprising: 1) contacting amorphous montelukast sodium or a mixture of amorphous montelukast sodium and montelukast sodium Form A with acetonitrile to form montelukast sodium:acetonitrile monosolvate; 2) collecting said monosolvate; and 3) removing acetonitrile from the collected monosolvate.

10

5

16. The method of Claim 14 wherein a mixture of amorphous montelukast sodium and montelukast sodium Form A is used in step 1).